4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–1967]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Biosimilars User Fee Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0718. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-3794, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Biosimilars User Fee Program

OMB Control Number 0910-0718--Extension

This information collection supports FDA's Biosimilars User Fee Program. The Biologics Price Competition and Innovation Act of 2009 (BPCI Act), amended the Public Health Service Act by adding section 351(k) (42 U.S.C. 262(k)) to create an abbreviated approval pathway for biological products shown to be biosimilar to or interchangeable with an FDA-licensed reference biological product. This allows a company to apply for licensure of a biosimilar or interchangeable biological product (351(k) application). The BPCI Act also amended section 735 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g) to include 351(k) applications as a type of application under "human drug application" for the purposes of the prescription drug user fee provisions.

The Biosimilar User Fee Act of 2012 (BsUFA) authorized FDA to assess and collect user fees for certain activities in connection with biosimilar biological product development (BPD). BsUFA was reauthorized for an additional 5 years in August 2017 (BsUFA II). FDA's biosimilar biological product user fee program requires FDA to assess and collect user fees for certain meetings concerning biosimilar BPD (BPD meetings), investigational new drug applications (INDs) intended to support a biosimilar biological product application, and biosimilar biologic license applications (BLAs).

Form FDA 3792, entitled "Biosimilars User Fee Cover Sheet", is submitted by each new BPD entrant (identified via a new meeting request or IND submission) and new BLAs. Form FDA 3792 requests the minimum necessary information to identify the request and determine the

amount of the fee to be assessed, and to account for and track user fees. The form provides a cross-reference of the fees submitted for an activity with the actual submission or activity by using a unique number tracking system. The information collected is used by FDA's Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research to initiate the administrative screening of biosimilar biological product INDs, and BLAs, and to account for and track user fees associated with BPD meetings.

In addition to the Biosimilars User Fee Cover Sheet, the information collection includes an annual survey of all BsUFA II participants designed to provide information to FDA of anticipated BsUFA II activity in the upcoming fiscal year. This information helps FDA set appropriate annual BsUFA II fees.

FDA has also developed the guidance entitled, "Assessing User Fees Under the Biosimilar User Fee Amendments of 2017" to assist industry in understanding when fees are incurred and the process by which applicants can submit payments. The guidance also explains how respondents can request discontinuation from the BPD program as well as how respondents can request to move products to the discontinued section of the biosimilar list. Finally, the guidance provides information on the consequences of failing to pay BsUFA II fees, as well as processes for submitting reconsideration and appeal requests. The guidance is available on our website at https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM584984.pdf.

In the *Federal Register* of June 29, 2018 (83 FR 30746), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden [1]

Information Collection Title	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (hours)	Total Hours
Biosimilar User Fee Cover Sheet; Form FDA 3792	35	1	35	0.5 (30 minutes)	17.5
Annual Survey	35	1	35	1	35
Request for discontinuation from BPD program	2	1	2	1	2
Request to move products to discontinued section of the biosimilar list	5	1	5	0.5 (30 minutes)	2.5
Total					57

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

We have increased our estimate by an additional 15 respondents since last OMB approval of the information collection. This estimated increase is based on our expectation that participation in the BPD program will continue to grow, consistent with our experience since establishment of the information collection in 2012.

Dated: October 30, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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